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| 10/766,068 | 01/28/2004 | Soichi Saito | WAKAB85.001AUS | 2422 |

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| EXAMINER | |
|---|---|
| VATHYAM, SUREKHA | |

| ART UNIT | PAPER NUMBER |
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| 1753 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/766,068 | SAITO ET AL. | |
| | Examiner | Art Unit | |
| | Surekha Vathyam | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/04, 7/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. Figures 8 and 9 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated per applicant's admission in instant specification pages 4 – 6. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

2. Claims 12 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Apparatus claim 12 recites structural limitations of chemical sensor and depends from claim 2, which is a method claim for the use of a chemical sensor. Similarly apparatus claim 13 depends from method claim 11. Neither of apparatus claims 12 and 13, further limit their

respective parent method claims. For purposes of examination each of claims 12 and 13 will be treated as independent apparatus claims.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of claims 12 and 13 recite "means for applying a bias" and "means for detecting a signal measured by the chemical sensor". Each of these means-plus-function claim limitations does not have corresponding structures described in the specification thereby failing to comply with the written description requirement.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 – 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In several instances of claims, after reciting that the method or apparatus comprises a limitation, the same claim or a dependent claim continues to recite the same limitation in more detail but recites it as the method or apparatus "further comprising" which makes it unclear if the claim requires the same element two times or should actually be reciting the limitation "further comprising" instead of the method or apparatus "further comprising" the details of the limitation. For example, in claim 12, the apparatus comprising: "means for applying a bias between the working electrode and the reference electrode" is recited followed by the apparatus further comprising: "a system for applying a first initial treatment bias... between the working electrode and the reference electrode"; "a system for changing the bias to be applied between the working electrode and the reference electrode". It is unclear if the means for applying bias claimed first is in addition to the system for applying bias claimed later or is further described in detail later. For purposes of examination, double recitations of the same limitation will be considered as single recitations since the specification only provides for such an interpretation.

7. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of claims 12 and 13 recite a "notification device" which the specification clearly defines as "displays such as LCD, sound, vibration, and the like". However the claims recite "the notification device comprising: a

system for applying a first... bias; a system for changing the bias". It is unclear how a display could apply bias or change bias.

8. Claim 3 recites the limitation "the counter electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 3 recites the limitation, "the steps of applying the measurement bias, the first initial treatment bias, and the second initial treatment bias are set respectively in such a manner that the difference between the biases of the reference electrode and working electrode in the buffer solution imparts the bias difference in accordance with the measurement bias, the first initial treatment bias, and the second initial treatment bias". It is unclear what if anything is being claimed by this limitation. It is previously stated in the claim that "a desired bias is applied between the working electrode and the reference electrode". So the limitation, "difference between the biases of the reference electrode and working electrode in the buffer solution imparts the bias difference" is unclear since a bias is applied and therefore cannot also give rise to a difference in bias between the working and reference electrodes, leave alone impart a "bias difference".

## *Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

NOTE: While it is unclear what is being claimed, as discussed above, the claims have been considered with regard to the prior art to the extent possible.

13. Claims 1 – 3, 5, 10 – 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al. (US 5,352,349) in view of Cozzette et al. (US 5,112,455).

Regarding claims 1 and 11, Inamoto ('349) discloses a method of measuring a concentration of a specific substance contained in a measurement sample (column 1,

lines 11 – 21) by use of a chemical sensor (see figs. 1, 2 and 6) comprising at least a working electrode (1) and a reference electrode (2), wherein the method comprises a first treatment step of applying a first treatment bias having the same direction as that of the measurement bias and possessing an absolute value larger than that of the measurement bias between the working electrode and the reference electrode for a predetermined first treatment time (see figs. 3 and 7 and column 8, lines 29 – 44); a second treatment step of changing the bias to be applied between the working electrode and a reference electrode to a second treatment bias which is the same as the measurement bias, after ending the first treatment step (see figs. 3 and 7 and column 8, lines 45 – 57); and the chemical sensor is immersed into the measurement sample (column 8, lines 58 – 64), and the measurement bias applied between the working electrode and the reference electrode is used to measure the concentration of the specific substance contained in the measurement sample based on a change in an amount of a current produced by an electrochemical reaction during measurement (see figs. 3 and 7 and column 8, line 45 – column 9, line 25). Inamoto ('349) discloses the method for reviving an electrode before using it with a measurement sample (column 1, lines 11 – 16). Inamoto ('349) does not explicitly disclose performing the treatment steps in a buffer though the explicit disclosure of the measurement sample being introduced to the sensor only after the treatment steps (column 12, lines 58 – 60) would have suggested it to one of ordinary skill in the art.

Cozzette ('455) teaches a method of measuring a concentration of a specific substance contained in a measurement sample (column 1, lines 41 – 45 and column 12,

lines 50 – 60) by use of a chemical sensor comprising at least a working electrode and a reference electrode (column 5, lines 42 – 56 and column 12, lines 6 – 10), wherein the method comprises at the stage of making first use of the sensor (column 7, line 63 – column 8, line 3) or at every stage post to continued use of the chemical sensor for a predetermined time (column 8, lines 29 – 38), a first treatment step of applying a first treatment bias possessing an absolute value larger than that of the measurement bias (column 22, lines 23 – 28) between the working electrode and the reference electrode to hold the chemical sensor in a buffer solution for a predetermined first treatment time (see figs. 4 and 5 and column 22, lines 13 – 45 and column 23, lines 25 – 65); a second treatment step of changing the bias to be applied (column 22, lines 23 – 28) between the working electrode and a reference electrode to a second treatment bias which is the same as the measurement bias (see figs. 4 and 5 and column 22, lines 13 – 45 and column 23, lines 25 – 65), after ending the first treatment step, while the chemical sensor is immersed in the buffer solution, and holding the chemical sensor in a standby state (see fig. 5b); and after the completion of the second initial treatment step, the chemical sensor is placed for the first time at the use for measurement of the measurement sample (see figs. 4 and 5 and column 22, lines 13 – 45 and column 23, line 25 – column 24, line 12); and the measurement bias applied between the working electrode and the reference electrode is used to measure the concentration of the specific substance contained in the measurement sample based on a change in an amount of a current produced by an electrochemical reaction during the measurement (column 22, lines 46 – 62).

It would have been obvious to one of ordinary skill in the art to have performed the initial treatment steps in a buffer in the method of Inamoto ('349) as taught by Cozzette ('455) because it helps determine a baseline signal which can be subtracted from the measurement sample signal for more accurate concentration determination of the analyte of interest.

Regarding claim 2, Inamoto ('349) discloses a predetermined second initial treatment time (column 8, lines 53 – 57).

Regarding claim 3, Inamoto ('349) discloses the chemical sensor further comprises a counter electrode (3) in addition to the working (1) and reference electrode (2); the reference electrode is constituted of a material having a predetermined chemical potential difference from the working electrode (column 7, lines 15 – 18) and the reference electrode is used as a reference to set the bias for the working electrode and the reference electrode (column 8, lines 48 – 50).

Regarding claim 5, Inamoto ('349) discloses the first initial treatment bias applied between the working electrode and the reference electrode is selected in a range of the applied bias which is larger than the measurement bias by 10% or more (see fig. 3and column 8, lines 29 – 57).

Regarding claims 10 and 16, Inamoto ('349) discloses the chemical sensor is an amperometric chemical sensor (see fig. 2) which has a working electrode (1), counter electrode (2) and a reference electrode (3) all formed on a substrate (13) and an enzyme electrode (1) comprising at least an immobilized film layer (15) disposed on the

surface of the working electrode used for current detection (column 7, line 51 – column 8, line 5).

Regarding claims 12 and 13, Inamoto ('349) discloses a chemical sensor type measuring apparatus (column 1, lines 11 – 21) comprising: a chemical sensor (see figs. 1, 2 and 6) having at least a working electrode (1) and a reference electrode (2); a signal detection circuit (see figs. 1 and 6) including at least means for applying a bias (7, 7a, 7b, 6a, 5a, 5, 4, 12) between the working electrode and the reference electrode (column 7, lines 19 – 20 and column 9, lines 47 – 61), and means for detecting a signal measured by the chemical sensor (column 9, lines 19 – 25); and the apparatus further comprising: a system for applying a first initial treatment (claim 12) or a first refresh treatment (claim 13) bias having same direction as that of the measurement bias and possessing an absolute value larger than that of the measurement bias between the working electrode and reference electrode for a predetermined time (column 7, lines 19 – 29 and column 8, lines 29 – 36); a system for changing the bias to be applied between the working electrode and the reference electrode to a second initial treatment (claim 12) or a second refresh treatment (claim 13) bias for a second treatment time (column 7, lines 19 – 50 and column 8, lines 45 – 50). Inamoto ('349) does not explicitly disclose a notification device.

Cozzette ('455) teaches a chemical sensor type measuring apparatus (column 1, lines 41 – 45 and column 12, lines 50 – 60) comprising a working electrode and reference electrode (column 5, lines 42 – 56 and column 12, lines 6 – 10); a signal

detection circuit including means for applying bias between the working electrode and the reference electrode (column 22, lines 13 – 62), and means for detecting a signal measured by the chemical sensor (column 15, lines 17 – 21 and column 22, lines 13 – 62); and the apparatus further comprising a notification device (see fig. 7 and column 12, lines 56 – 60, column 13, line 68 – column 14, line 2 and column 16, lines 60 – 68) comprising a system for notifying that the chemical sensor is ready (see figs. 7 – 9 and column 15, line 50 – column 16, line 68).

It would have been obvious to one of ordinary skill in the art to have included the notification device as taught by Cozzette ('455) in the apparatus of Inamoto ('349) because it helps alert users of the apparatus of spikes, glitches, noise or observed values falling outside an expected range while using the apparatus as explained by Cozzette ('455).

14. Claims 4, 6 – 9, 14 – 15 and 17 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al. (US 5,352,349) in view of Cozzette et al. (US 5,112,455) as applied to claim 3 above, and further in view of Matsumoto et al. (US 5,795,774).

Regarding claim 4, Inamoto ('349) discloses a silver electrode is used as the reference electrode and a platinum electrode is used for the working electrode (column 7, lines 15 – 18) and said measurement bias applied between the working electrode and the reference electrode during the measurement is an applied bias obtained by the bias

of the working electrode selected on the datum basis of the silver electrode used as the reference electrode (column 1, lines 44 – 46, column 8, lines 45 – 50). Inamoto ('349) does not explicitly disclose that a silver/silver chloride electrode is used as a reference electrode or that platinum electrode is used for the counter electrode or that the measurement bias is from a range of 400 to 700 mV.

Matsumoto ('774) teaches a method of measuring a concentration of a specific substance contained in a measurement sample by use of a chemical sensor (column 1, lines 6 – 13) comprising a platinum electrode that is used for the working electrode (10) and counter electrode (11) and a silver/silver chloride electrode that is used as the reference electrode (12) (column 7, line 45 – column 8, line 12).

It would have been obvious to one of ordinary skill in the art to have used the silver/silver chloride reference electrode and platinum counter electrode in the sensor of Inamoto ('349) as taught by Matsumoto ('774) because the silver/silver chloride electrode lends itself to sputtering methods which offer the lowest cost and greatest ease of manufacture and thus most suitable for large volume production and platinum displays excellent conductivity and is also highly acid and chemical resistant which make it a highly desirable electrode material as explained by Matsumoto (column 7, line 59 – column 8, line 12).

Cozzette ('455) teaches the range of applied bias for measurement is a variable for optimization based on the needs of the particular application (column 22, lines 29 – 31).

It would have been obvious to one of ordinary skill in the art to have selected a particular range of values for the applied bias because applied bias is recognized as a variable for optimization (column 22, lines 29 – 31 of Cozzette ('455)). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 6 – 9 and 14, Inamoto ('349) discloses in the first treatment step, the first initial treatment bias applied between the working electrode and the reference electrode is selected to be higher than the measurement bias and is recognized as a parameter for optimization (column 8, lines 29 – 36) as are the first and second initial treatment times (column 8, lines 37 – 44 and column 8, lines 51 – 57). Inamoto ('349) does not explicitly disclose the applied bias ranges and initial treatment times.

It would have been obvious to one of ordinary skill in the art to have selected a particular value for applied bias and initial treatment times because these parameters are recognized as variables for optimization. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 15, 17 – 20, Inamoto ('349) discloses the chemical sensor is an amperometric chemical sensor (see fig. 2) which has a working electrode (1), counter electrode (2) and a reference electrode (3) all formed on a substrate (13) and an enzyme electrode (1) comprising at least an immobilized film layer (15) disposed on the surface of the working electrode used for current detection (column 7, line 51 – column 8, line 5).

## *Conclusion*

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Burleigh et al. (US 4,734,184), Lauks et al. (US 5,096,669), Johnson et al. (US 5,411,647)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SV/
17 September 2007

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